SUBMISSION TO THE PRODUCTIVITY COMMISSION STUDY INTO CHEMICALS AND PLASTICS REGULATION

Department of Agriculture, Fisheries and Forestry

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1. INTRODUCTION

The Department of Agriculture, Fisheries and Forestry has a national leadership role in the development and implementation of agricultural and veterinary (agvet) chemicals and fertiliser policy. It provides the chair and secretariat to the Product Safety and Integrity Committee (PSIC) which provides policy advice to the Primary Industries Ministerial Council (PIMC) on agvet chemicals and fertiliser policy issues. The Department is also responsible for administering the legislation under which the Australian Pesticides and Veterinary Medicines Authority (APVMA) operates. However, the APVMA is responsible for its day-to-day operational matters.

Therefore, the Department's submission is mainly focussed on agvet chemical regulations developed through PSIC, noting that controls on agvet chemicals go beyond those for which PSIC/PIMC, is responsible. Fertilisers are only considered in the context of the current regulations applying to security sensitive ammonium nitrate (SSAN).

Agvet chemicals are used to protect crops, livestock, other animals and plants, from pests and diseases. They are also used in the wider community to control weeds and pests in gardens, national parks and nature reserves and to protect public health by helping to control disease carrying insects (eg mosquitos). Agvet chemicals are important agricultural inputs in that they help agricultural industries be more productive and competitive on world markets and improve product quality. Users (farmers and commercial applicators - ground, aerial and pest controllers) need access to these chemicals since they rely upon for them their livelihood. Chemical manufacturers and distributors need to be able to market chemical products to remain economically viable.

Agvet chemicals can also have unwanted side effects. Therefore, governments (on behalf of the general community) have a responsibility to ensure the potential human health and environmental risks of using them are managed. To this end, an overarching national framework has been established - the national agvet chemical management system. It has a number of elements including the National Registration Scheme for Agricultural and Veterinary Chemicals (NRS) as well as industry programs and provides a basis for achieving a streamlined and harmonised system for managing agvet chemicals. PSIC has published a brochure which sets out the objectives of the system and which outlines the roles and responsibilities of government and non-government stakeholders in managing the potential risks associated with agvet chemicals and their use, including health and environmental agencies involved in evaluating agvet chemical products. A copy of the brochure is attached. It can also be accessed through the PSIC web page on the Departmental website (www.daff.gov.au/psic) and on the APVMA's website.

An important element of the agvet chemical management system is system evaluation and improvement. PSIC is progressing a number of initiatives designed to improve the national system. Where regulation is needed to manage these risks, PSIC seeks to do so in a way which

- minimises the costs to stakeholders

- maintains Australia as an attractive market for chemical manufacturers, particularly for chemicals needed by producers of specialty/minor crops
- encourages the introduction of new chemicals, particularly those which are lower risk.

In recognition of the fact that governments do not have unlimited resources, PSIC has developed a risk assessment framework to identify the policy areas which present the greatest risk to achieving the objectives of the agvet chemical management system and which will contribute most to its improvement in a cost effective way. However, it is acknowledged that achieving agreement on national policy approaches is sometimes difficult. In addition, because other regulatory schemes are outside PIMC's jurisdiction, also impact on non-government agvet chemical stakeholders, it is difficult for PSIC alone to make the necessary improvements.

In this submission, the Department

- outlines the national regulatory framework already in place for managing the risks associated with agvet chemicals
- outlines stakeholder concerns and the work being progressed by PSIC to address them
- notes that there are some impediments to regulatory reform
- identifies areas where improvements could be made
- outlines other issues which have implications for agvet chemical regulation.

2. REGULATIONS AFFECTING AGVET CHEMICAL USERS, MANUFACTURERS AND DISTRIBUTORS

Agvet chemical users, manufacturers and distributors are impacted by regulations at all levels of government. They are administered by different portfolios for different purposes and deal with the safe use, handling, storage, transport and disposal of chemicals. A large number of agvet chemical users and distributors also use/handle fertilisers and, therefore, are subject to regulations to ensure that SSAN is transported and stored securely.

Under the NRS, the APVMA regulates the manufacture, distribution and supply of all agvet chemical actives and products up to, and including, the point of retail sale. Companies wishing to register a product must submit an application for registration supported by the data required to assess the product. The result of this assessment is a product label which includes instructions for its handling and use and may also place conditions on the use of the product. Implementation of the GHS for agvet chemicals would have an impact on the information included on the label. Issues surrounding the GHS are discussed under 'Other Issues'.

In addition to registering new agvet chemicals, the APVMA undertakes activities including

- routine and targeted reviews of the registration of existing chemicals
- granting of permits for various reasons including so that chemicals can be used in ways not included on the label (off-label use) and so that they can be used by

producers of speciality crops (minor use) where no registered chemical control options are available
- ensuring that chemicals in the market place comply with their stated formulation and labelling.

Through the registration of chemical products, the APVMA determines which chemicals are available to users and the way they can be used. In addition, because the APVMA's review process may remove products from the market or change the way they can be used, it has the potential to affect product sales for manufacturers and distributors and the availability of chemicals to users. The availability of chemicals is also affected by the granting of permits by the APVMA for particular off-label uses and for minor uses.

Under the NRS, state/territory governments are responsible for ensuring that users comply with the label instructions and conditions of use. This is done through Control of Use (COU) legislation. The regulatory requirements under this legislation vary from jurisdiction to jurisdiction but may include
- licensing schemes covering commercial applicators
- training for agvet chemical users
- notification and record keeping requirements with respect to chemical spraying
- the need for users of certain higher risk chemicals to be authorised.

In addition to the NRS, there is a number of other regulatory schemes which affect agvet chemical users, manufacturers and distributors. These cover OHS, environment protection, poisons scheduling, dangerous goods – it is noted that work is being progressed on the application of restrictions similar to those for SSAN to chemicals of security concern.

3. STAKEHOLDER CONCERNS WITH THE CURRENT REGULATORY ARRANGEMENTS

Through the annual PSIC stakeholder workshops, the Banks Task Force, the PC Study into the Regulatory Burdens on the Primary Sector and the Australian National Audit Office's (ANAO) performance audit of the APVMA, a number of areas have been identified where users, manufacturers and distributors consider regulation poses unnecessary costs. These are outlined below. Some are common to both sets of stakeholders and it is noted that those of concern to manufacturers and distributors may also affect users because of the potential impact on the cost of chemical products.

Users - farmers and commercial applicators (aerial, ground and pest exterminators)

- Agvet chemicals are not available for minor uses.
- Withdrawal of chemicals from the market as a result of reviews by the APVMA.
- Agvet chemicals which are available to overseas competitors are not available in Australia.
- The overlap and duplication of regulations which are administered and enforced by different portfolios but have the same/similar objectives and requirements for

chemicals to be used, transported, handled, stored and disposed of safely and, in the case of fertilisers, that they are transported and stored securely.
- Inconsistent and inadequate enforcement by the states/territories for compliance with COU regulations may lead to the withdrawal of chemical products from the market because of their misuse.
- Inequities because users in one jurisdictions are subject to different regulatory requirements to those in other jurisdictions.
- Those that operate in more than one jurisdiction must comply with more than one set of regulatory requirements.

Manufacturers and Distributors

- Timeliness of the APVMA's registration process.
- The amount of data required for assessments.
- Inability to use relevant data generated for the registration of same/similar products overseas.
- Because chemicals are regulated on the basis of use, producers of the same/similar products with different uses, must deal with more than one regulator which may have different requirements. For example, an antibiotic which claims to treat cattle is regulated by the APVMA but antibiotics used to treat humans are regulated by the TGA.
- The overlap and duplication of regulations which are administered and enforced by different portfolios but have the same/similar objectives and requirements**.**
- Inconsistent and inadequate enforcement by the states/territories for compliance with COU regulations may lead to the withdrawal of chemical products from the market because of their misuse.
- Use of chemicals in ways that aren't approved on the label may also lead to the withdrawal of chemical products from the market if an incident occurs as a result.

4. ADDRESSING STAKEHOLDER CONCERNS

Initiatives are currently being progressed by PSIC, the APVMA and DAFF which seek to address a number of the concerns raised by stakeholders.

Those being progressed by PSIC have been identified in a number of ways including: on the basis of a formal risk assessment; in response to recommendations of reviews and reports; and through feedback received from stakeholders. In all cases, the policy approaches being developed recognise the need to keep costs to a minimum by ensuring that the level of regulation is the minimum necessary to meet the policy objectives of governments and that it is nationally harmonised/consistent.

PSIC has developed a risk management framework as a basis for determining its workplan priorities. The framework identifies the detailed risks associated with agvet chemical use (broadly categorised as the risks to human health, the environment industry competitiveness and trade/market access). It allows an assessment to be made of the consequences of not managing those risks and the likelihood of them occurring - taking into account the extent to which existing strategies are managing

the risks. At state/territory level, these strategies include inspection, targeted residue monitoring programs and existing primary industry quality assurance programs and codes of practice.

Using the framework, PSIC has identified user awareness and training as a key factor in ensuring that the risks of agvet chemical use are managed. However, recognising that mandatory training imposes costs and that primary industry quality assurance programs and codes of practice often already include a training element, attention is currently being focused on developing a scheme for users of those chemicals which present a higher level of risk – as determined through the application of criteria being developed in consultation with government and industry stakeholders. Consideration will then be given to the costs and benefits of extending this scheme to users of other (lower risk) chemicals.

In addition to managing the risks of agvet chemical use, this work should help to address concerns regarding the possible withdrawal of chemicals from the market as a result of routine reviews by the APVMA because access and use conditions would already be in place to manage the risks. This may also mean that an adverse incident, which might trigger a review, is less likely to occur.

Another priority area identified using the risk assessment framework is the development of a performance measurement framework to evaluate the effectiveness of policies/strategies in managing the risks and to underpin public confidence in the agvet chemical management system. It includes the following outcomes against which performance can be measured

- Australian primary produce meets both domestic and international MRLs and other standards
- exported Australian produce meets the importing country MRLs
- produce imported into Australia meets Australian MRLs
- minimal adverse experiences from legal agvet chemical use
- reduced risk options for pest and disease control are adopted
- off-target spray drift incidents on primary produce are avoided
- unacceptable residues in potable water are avoided
- adverse, non-occupational, public health incidents from contact with pesticides are avoided
- adverse occupational health and safety health effects are avoided
- unacceptable residues in surface water, groundwater and raw water are avoided
- adverse environmental impact from off-target spray drift are avoided
- off-target wildlife and companion animal deaths are avoided.

An initial assessment by states/territories of their performance against the indicators established for each performance outcome suggests that there are three areas where performance may need to be improved - exported Australian produce meets the importing country MRLs; off-target spray drift incidents on primary produce are avoided; and adverse, non-occupational, public health incidents from contact with pesticides are avoided. Before considering options for making improvements in these areas, PSIC is progressing work to determine the extent to which the framework provides a reliable assessment of performance – including, whether more, or better,

data is needed and the effect on performance outcomes of government/industry capacity to respond to incidents.

An essential part of performance measurement is the availability of data. To help target resources for monitoring, by relevant agencies/portfolios, for possible environmental, human health and trade impacts, PSIC is undertaking work on the collection of usage data for a number of chemicals identified as being of concern. This will provide information on where they are used, on what crop, when and in what quantities. As part of this process, a pilot study is being conducted by the Tasmanian Government to assist PSIC determine the costs of collecting usage data and whether there are benefits in extending this to the rest of Australia.

The Tasmanian pilot study is also informing the process being conducted by the Department of Environment and Water Resources (DEW) to develop a national chemicals monitoring database under the NChEM framework. The intention is that the NChEM database will collect data on the post-use impacts of agvet and industrial chemicals on the environment. PSIC is working cooperatively with DEW, as a member of the National Chemicals Monitoring Database Steering Committee, since monitoring data obtained through this initiative would contribute to PSIC's work on performance measurement.

In addition to the initiatives discussed above, PSIC is progressing work in a number of other areas. For example, in response to recommendations of the NCP Review of Agvet Chemical Legislation, a national system for pilots and businesses involved in the aerial application of agvet chemicals is being developed with a view to reducing costs to both pilots and businesses whilst ensuring that the regulatory objectives continue to be met.

Further, in response to stakeholder feedback, work is being progressed to reduce the cost of registering agvet chemicals. To this end, a framework has been developed against which products captured by the definition of an agricultural or veterinary chemical product can be assessed to determine whether they need to be regulated and, if so, whether the APVMA or another agency, such as NICNAS or the TGA, is the appropriate regulator.

Where other regulations are already effectively managing the risks associated with a product (eg state/territory occupational health and safety or food safety regulations) or the risks associated with a product are so low that regulation is not warranted, the product will not be regulated. If a product needs to be regulated in order to manage the risks, but another agency has been identified as the appropriate regulator, the APVMA will negotiate the transfer of responsibility for regulating that product. If the alternative regulator does not agree to the proposed transfer, the APVMA will continue to regulate the product.

For those products which the APVMA should regulate, the framework enables a decision to be made on the appropriate level of registration based on risk - full registration, listed registration or reservation from registration. Fewer data are required for listed registration and reservation from registration than for full registration. This differentiation in levels of registration should bring the amount of data required by the APVMA for listed registration and reservation from registration

of products more into line with the data requirements of other regulators for products of low regulatory concern. This will help address industry concerns that different regulators have different data requirements even though the products are the same/similar.

Further, as part of this work, the process by which products of low regulatory concern are listed as registered or reserved from registration is being streamlined. Under the proposed new arrangements, subject to consultation with relevant state/territory departments and the general public, the CEO of the APVMA, rather than the Minister for Agriculture, Fisheries and Forestry, would be able to approve the standards and conditions for products to be listed as registered or reserved from registration. DAFF is currently examining the legislative implications of these proposed arrangements with a view to implementing an appropriate supporting framework. This would mean that products of low regulatory concern can be registered more quickly by removing the need for regulations to be made. In this regard, it is noted that, although the current arrangements were introduced in 2003, the first products of low regulatory concern have only recently been registered.

In addition to the above initiatives by PSIC, the APVMA is making a number of operational improvements in response to the recommendations of the 2006 ANAO audit which assessed whether the agency was delivering its key regulatory functions effectively. We expect that the APVMA submission will provide details of the improvements it is making in response to the recommendations.

Concerns about the availability of agricultural chemicals for use on specialty crops (minor use), are already being addressed by the APVMA and DAFF who provided resources to establish the Minor Use Liaison Office (MULO) in August 2006. MULO is working to extend existing registrations to specialty crops and to rationalise permits. This should also address concerns regarding the use of chemicals off-label. MULO is developing a gap analysis of chemical control options for specialty cropping industries in Australia which will be used, at the end of the first year of its operation, to recommend to governments and industry a long-term structure for addressing minor use needs.

User and manufacturer concerns that state/territory enforcement of compliance with COU regulations is inconsistent and inadequate have been made known to PSIC at stakeholder workshops in recent years. PSIC recognises the importance of ensuring that the nationally agreed regulatory objectives of COU regulations are achieved and that this be done in a cost efficient and effective way.

A number of stakeholders have suggested that enhanced and nationally consistent enforcement arrangements are needed to ensure that users comply with the regulations so that chemicals are not misused and, therefore, possibly withdrawn form the market. However, consistent with current co-regulatory approaches used by governments and in line with COAG's outcomes-based approach to regulation, PSIC recognises that industry, as well as government, has a role in ensuring chemicals are not misused. For instance, many primary industry sectors already have programs in place which include requirements for managing the risks associated with the use of agvet chemicals in their operations. Some, including the cotton industry and pilots applying agricultural chemicals aerially, have programs specifically designed to manage these

risks. In addition, primary producers supplying commercial retailers such as Coles and Woolworths must meet particular requirements with regard to agvet chemical use.

Under the NRS, it is the responsibility of individual states/territories to determine which strategies are necessary, or appropriate, to achieve the regulatory objectives in their jurisdiction. While compliance and enforcement arrangements and the level of resources committed to them may vary between jurisdictions, there are often good reasons for this. For example, certain chemicals of concern may only be used in jurisdictions where particular crops are grown - cotton is grown only in NSW and Queensland - or where particular pests or diseases need to be controlled.

Compliance is achieved by encouraging industry ownership and responsibility for managing the risks, rather than relying solely upon inspection. Farmers and commercial applicators know that it is in their interests to use chemicals safely because, otherwise, they put their livelihoods at risk. Government oversight is maintained through monitoring and reporting programs as a part of performance measurement. If industry/market driven risk management arrangements are found to be unsatisfactory, increased government intervention may be necessary**.**

5. BARRIERS TO REFORM

With responsibility for regulating COU resting with the states/territories, governments have acknowledged the need for harmonisation and have established PSIC to develop national policy approaches (including regulatory policy) for improving the management of agvet chemicals. PSIC recognises that regulation imposes costs for all stakeholders and that these costs need to be kept to a minimum. The national regulatory reforms (noted above) being progressed by PSIC seek to harmonise state/territory COU regulation and reduce the cost of regulation in a number of areas. However, it can be difficult for PSIC to deliver reforms within a timeframe considered acceptable by non-government stakeholders, due to a number of factors including

- difficulty in achieving agreement on policy approaches when
  - responsibility for the regulation of agvet chemicals under the National Registration Scheme rests with governments at national and state/territory levels
  - different portfolios are involved in COU regulation which may result in policy proposals developed by PSIC having to take into account different approaches to risk
- different jurisdictions having different priorities and political imperatives which affects the level of resources directed towards agvet chemical work
- states/territories need the flexibility to be able to respond individually to situations that occur within their jurisdiction
- PSIC has a diverse range of stakeholders with different expectations and different views on risk management
- periodic reviews of COU legislation undertaken by states/territories individually, rather by through PSIC, can lead to different COU requirements in different jurisdictions.

6. AREAS WHERE IMPROVEMENTS COULD BE MADE

Although reforms may not be progressed as quickly as users, manufacturers and distributors would like, PSIC does provide a mechanism for developing and implementing national policy approaches to harmonise COU regulation for agvet chemicals at minimal cost to industry and government. However, the Department is not certain to what extent regulatory schemes administered by other Ministerial Councils, but which also apply to agvet chemicals, are already harmonised or whether their harmonisation is being progressed by these Councils.

In the case of COU regulation, if the costs to stakeholders are determined to be sufficiently large, there may be value in considering transferring responsibility for this aspect from the states/territories to the APVMA which could then contract a third party (possibly the existing state/territory regulatory authorities) to undertake these activities on its behalf. In establishing the NRS over a decade ago, states/territories agreed to transfer responsibility for agvet chemical assessment and registration to the Commonwealth (the APVMA), while retaining responsibility for regulating COU. It may now be opportune to consider consolidating all activities relating to the registration, sale and use of agvet chemicals within the APVMA.

While the differences in COU regulation between states/territories are of concern to stakeholders, cross-portfolio overlap and duplication of regulatory requirements at state/territory level appear to be the area where greatest concern rests, particularly for users. Therefore, the Department believes that the greatest benefit is likely to be achieved by reducing the complexity of regulation at the state/territory level, rather that changing existing Commonwealth structures.

One way in which this could be done is by reviewing the requirements of the different regulatory schemes to determine those which they have in common and the extent to which cross-portfolio recognition of existing programs/initiatives could be used to meet shared risk management objectives. Where primary industry sectors (users), manufacturers and distributors already have arrangements in place for meeting these requirements (for example, quality assurance programs and codes of practice), these could be recognised as being appropriate for meeting the requirements of other regulatory schemes. In this way, the costs of compliance with the requirements of the different regulatory schemes would be reduced.

An example of this approach is the way the requirements of the Food Hygiene Standards, developed by FSANZ, are met. The standards are applied by state/territory Food Acts which require primary food producers, food processors and food retailers to meet the objectives of the Act (ie to produce safe and suitable food). The Food Acts recognise that primary producers can meet their food safety obligations though industry quality assurance programs or codes of practice, rather than by complying with the Food Safety Regulations.

Further rationalisation of the regulatory requirements of different portfolios/agencies could be achieved by establishing a mechanism for cross-portfolio discussion of policy approaches or for generating awareness and understanding of programs and

initiatives already in place which could be used to meet common risk management objectives. Improved cross-portfolio coordination would acknowledge that, whilst the some of the risk management objectives of the different chemical regulatory schemes are the same or similar, they have different purposes and, therefore, they also cover other aspects. For example, OH&S regulation has much broader coverage than management of the OH&S risks posed by chemicals.

Consideration needs to be given to whether cross-portfolio harmonisation would best be addressed at the individual states/territories level or at the national level. Some models already exist for facilitating this kind of coordination. For example, at the Australian Government level, the Chemicals Clearing House coordinates Australian cross-portfolio input into the development and implementation of international chemical standards and regulations. The Department understands that Western Australia has established a mechanism for coordinating cross-portfolio regulation of chemicals in that State.

If done at the national level, coordination could achieve the outcomes sought by the national chemicals policy proposed by industry, in that it would deliver clearly defined outcomes, identify roles and responsibilities and reduce fragmentation and complexity. In this regard, it is noted that the national agvet chemical management system, outlined in the 'Introduction' could provide a useful model for a national chemicals policy.

Improved cross-portfolio coordination could also allow for better coordination between national regulators and facilitate the identification of an appropriate regulator and streamline assessment processes, including through data sharing and work sharing. In this way, it could address industry concerns about the costs of compliance with the different regulatory requirements imposed by different national regulators for the same or similar products.

Given the benefits that could arise from improved cross portfolio co-ordination and recognition of existing programs/initiatives, it is of some concern that the Australian Safety and Compensation Council (ASCC) has proposed withdrawing its recognition of the APVMA labelling code with respect to meeting the requirements of its occupational health and safety legislation. This proposal appears to be inconsistent with initiatives to rationalise existing chemicals regulation. Therefore, in the first instance, it might be worthwhile determining how the APVMA labelling code could be changed to accommodate the needs of OH&S regulators, rather than no longer recognising it as appropriate.

The agvet chemical management system is designed to manage the potential human health and environmental risks associated with agvet chemical use. It is noted that insufficient information about the environmental fates of chemicals has resulted in a more risk averse approach to environmental risk assessment, which ultimately disadvantages both industry and users. The Department strongly supports initiatives to improve environmental risk management, including the NChEM objective to standardise environmental risk assessment methodologies to improve consistency and transparency and increase the involvement of State/Territory environmental agencies in the risk assessment process. It is noted that other possible strategies could include

- a nationally coordinated research effort aimed at determining the impact of chemicals on the environment
- accessing the latest research and international practices in relation to those impacts
- developing a nationally coordinated approach to research into improved risk assessment methods.

7. OTHER ISSUES

i. Globally Harmonised System of Classification and Labelling of Chemicals

In providing comments on the GHS, the Department has answered the specific questions raised by the Productivity Commission in its September 2007 issues paper.

Should the GHS be implemented across all sectors of the chemicals and plastics industry, including agricultural and veterinary chemicals and scheduled drugs and poisons?

Australia's long standing comprehensive approach to the classification, risk assessment and labelling of agvet chemicals is comparable to the pesticide regulatory systems of many developed countries. The approach effectively manages the human health and environment risks of chemical use according to world's best practice and has no demonstrable gaps. Work is continuing to determine whether the adoption of the GHS (either partially or wholly) would enhance the regulation of these 'defined-use' products and their safe management by end-users and others.

If the GHS was not implemented for agvet chemicals, Australia would not benefit from the enhanced protection of human health and the environment through an internationally consistent and comprehensible system for hazard classification and communication. This could reduce the potential for mutual recognition of hazard classifications by other countries and affect the small amount of trade in pesticide products. In addition, the Banks report on reducing regulatory burden on business recommended that any uniquely Australian variation of international standards relating to the regulation of chemicals should demonstrate a net public benefit. As discussed in the GHS document, the competent authority for each chemical sector should determine if, and in what form, the GHS would be adopted.

What should influence decisions about the timing of the implementation of the GHS?

As discussed with major stakeholders for agvet chemicals, it is important to keep abreast of and in step with international implementation of the GHS as there is little advantage of implementing ahead of other countries. New Zealand had already adopted the GHS but has experienced some difficulties in implementation. The EU has proposed to adopt the GHS for pesticides with a final co-decision expected by the European Parliament and European Council before the end of 2008. Japan has decided not to implement the GHS for pesticide. Other countries are still considering the implications of implementation. Australia is leading the discussion at the UN

Sub-Committee of Experts on the GHS (SCEGHS) and APEC on issues to consider in implementation of the GHS. It is expected that these discussions will inform decisions on the timing of GHS implementation.

Should Australia wait until the system has been implemented by our major trading partners, or aim to be a leader in adopting the new system?

There is unlikely to be much benefit from adopting the GHS ahead of our major trading partners and many stakeholders believe we should wait for our major chemical trading partners to adopt it to allow access to classifications, data and experience.

What are the implications of transposing the hazard-based GHS system onto Australia's approach to classifying and labelling chemicals?

Initial considerations and feedback from the agvet chemical industry suggest that adopting the GHS classification (as opposed to labelling) would not compromise our current risk-based system and there may be benefits in harmonising with overseas regulatory counterparts to increase joint reviews and work sharing of pesticide assessments. However, adopting the four GHS labelling elements of hazard statements, precautionary statements, signal words and pictograms is more complex. The hazard and precautionary statements are similar to current agvet label information and adopting the GHS statements to harmonise with overseas systems may be beneficial. The different GHS signal words and new pictograms require further work to determine whether they would improve or detract from the current system.

In any case, agvet labels currently contain a mixture of risk-based and hazard-based information. Harmonising the current hazard-based information with the GHS hazard information would not seem to have major implications.

Overall, what will be the costs and benefits of implementing the GHS in Australia?

The Product Safety and Integrity Committee established a GHS Reference Group of agvet chemical stakeholders to discuss the implications of implementing the GHS. Below, some of the costs and benefits are outlined and how they might be dealt with.

CHEMICAL MANUFACTURERS	**COMMENTS**
Cost:	
Increased costs from printing new labels for existing registered products.	New labels are required when, for example, companies apply to the APVMA to change the conditions of use. As DEWR require MSDSs to be updated every five years with current OHS information, it may be possible that labels could be aligned and a suitable phase in period linked to this timeframe could be applied to ease costs.
Benefit:	
Improved international trade for chemicals.	Australia conducts little international trade in agricultural chemical products since they are registered and labelled for specific uses in this country. Therefore, trade benefits may be minimal except for active ingredients and concentrates.
Products classified overseas wouldn't need reclassification in Australia.	Products would still need to be scheduled by the NDPSC and registered by the APVMA.

CHEMICAL RETAILERS/DISTRIBUTORS **Cost:** Would need to learn what the new label wording and pictograms mean.	**COMMENTS** The GHS pictograms are part of the standard pictogram set used in the *UN Recommendations on the Transport of Dangerous Goods, Model Regulations* and the ADG Code and, therefore, are generally well understood. GHS hazard and precautionary statements are very similar to the risk and safety phrases currently used. A communication strategy could be developed which takes advantage of existing education and training programs, eg. Chemcert.
CHEMICAL USERS **Cost:** Some may perceive the label to be more detailed or complex which may be difficult to follow.	**COMMENTS** The APVMA is currently conducting a label review which could consider how the new GHS label elements can be incorporated.
Would need to learn what the new label wording and pictograms mean.	The GHS was designed with comprehensibility in mind. The pictograms are part of the standard set used in the *UN Recommendations on the Transport of Dangerous Goods, Model Regulations* and the ADG Code and, therefore, are generally well understood. GHS hazard and precautionary statements are very similar to the risk and safety phrases currently used. A communication strategy could be developed which takes advantage of existing education and training programs, eg. Chemcert, and could also be part of manufacturers' product stewardship.
Confusion if existing chemical labels are marketed alongside the new GHS-based labels.	Several versions of a label for the same product may be in the market place at a given time because a registrant may apply to have the product used on different crops or for different pests. If approved, these uses are included on a new label but old stock is not recalled. An implementation strategy (including a national public education program) with a designated timeframe could be implemented.
Benefit Easy to identify that the chemical poses a potential hazard if the chemical is not used according to label instructions.	Hazards are uniformly identified across all chemical types, eg. fuels, cleaners, etc, that farmers may encounter.
GOVERNMENT - APVMA **Cost:** Amending legislation The need to GHS classify and label chemical products that are currently registered. Additional costs from OCS and CAS would be passed on to the APVMA. **Benefit:** Classifications conducted overseas could be used in Australia.	**COMMENTS** Could phase in and align with DEWR's requirement that MSDSs are updated every five years for OHS purposes. May affect application fees to manufacturers Will facilitate international harmonisation and worksharing arrangements for assessing applications.

GOVERNMENT - OCS/DoHA	COMMENTS
Cost New classification arrangements. **Benefit:** Classifications conducted overseas could be used in Australia.	Classification methods are currently reviewed from time to time. Scheduling and toxicological risk assessments would still be required.
GOVERNMENT - CAS/DEH	**COMMENTS**
Cost New classification arrangements. **Benefit:** Classifications conducted overseas could be used in Australia.	Classification methods are currently reviewed from time to time. Environmental risk assessments would still be required.
GENERAL COMMUNITY **Cost:** **Benefit** Enhanced human health and environment protection through an internationally comprehensible system for hazard communication.	**COMMENTS** General education programs would be required to address a wide user group.

ii. NCHEM

The intent of the proposed NChEM framework is to streamline and improve national consistency in the environmental management of chemicals and improve environmental outcomes. The NChEM proposal aims to accomplish these objectives through four key action areas

1. standardising environmental risk assessment methodologies to improve consistency and transparency and increasing the involvement of State/Territory environmental agencies in the risk assessment process
2. ensuring that environmental controls are agreed and consistent across jurisdictions (relevant only to industrial chemicals)
3. enhancing information collection and feedback mechanisms, including additional reporting requirements
4. improving mechanisms to identify and address priority and emerging chemical-related environmental issues and enabling the Environment Protection and Heritage Council (EPHC) to be more proactive in raising environmental issues.

The NChEM proposal acknowledges that the NRS already addresses many of the key issues identified by the NChEM framework, and provides most of the elements required for best practice management of the environmental impacts of agricultural and veterinary chemicals. As a result, the NChEM proposal focuses mainly on the industrial chemicals management system, with some targeted improvements to the agvet chemicals management system, in particular, better environmental protection agency input into the environmental risk assessment process.

PSIC's concern that the NChEM framework could duplicate the systems already in place within the regulatory framework of the National Registration Scheme for agricultural and veterinary chemicals has been acknowledged by the EPHC, which is

working with the APVMA to ensure that this does not occur. PSIC has also observed that many of the concerns about agvet chemical management raised by state/territory conservation agencies and environment protection agencies were the result of a lack of awareness and understanding of the arrangements in place to manage the risks of agvet chemical use. To address this, brochures providing an overview of Australia's agvet chemical management system have been circulated to them.

The reforms proposed under the NChEM framework are linked to a number of issues affecting agvet chemical regulation, including concern that agvet chemicals might, in the future, be included in the National Pollutant Inventory (NPI), data collection and performance measurement initiatives being progressed by PSIC and improving environmental risk assessments for agvet chemical products.

PSIC strongly supports those aspects which are designed to improve the quality of the environmental risk assessments for agvet chemicals provided by the Department of the Environment and Water Resources (DEW). As noted earlier, PSIC also supports the development of the proposed chemical monitoring database, given that access to usage and monitoring data is needed to inform an effective performance measurement system and to support continuing the exclusion of agvet chemicals from the NPI.

iii. National Pollutant Inventory

Knowing where the sources of emissions are and whether they are emitted to air, water or land is the first step in assessing the nature of pollution in Australia. The NPI provides industry, governments and the community with comprehensive, free and easy access to information on the types and amounts of emissions into the Australian environment. NPI data assists government with environmental planning and management, while industry can use it to learn more about their processes and to introduce new cleaner production techniques.

Agvet chemicals were originally excluded from the National Pollutant Inventory (NPI) for a number of reasons, including that agvet chemical usage data would be collected through alternative mechanisms. Government and industry were also concerned that inclusion of agvet chemicals in the NPI would categorise them as pollutants, rather than as a beneficial agricultural input.

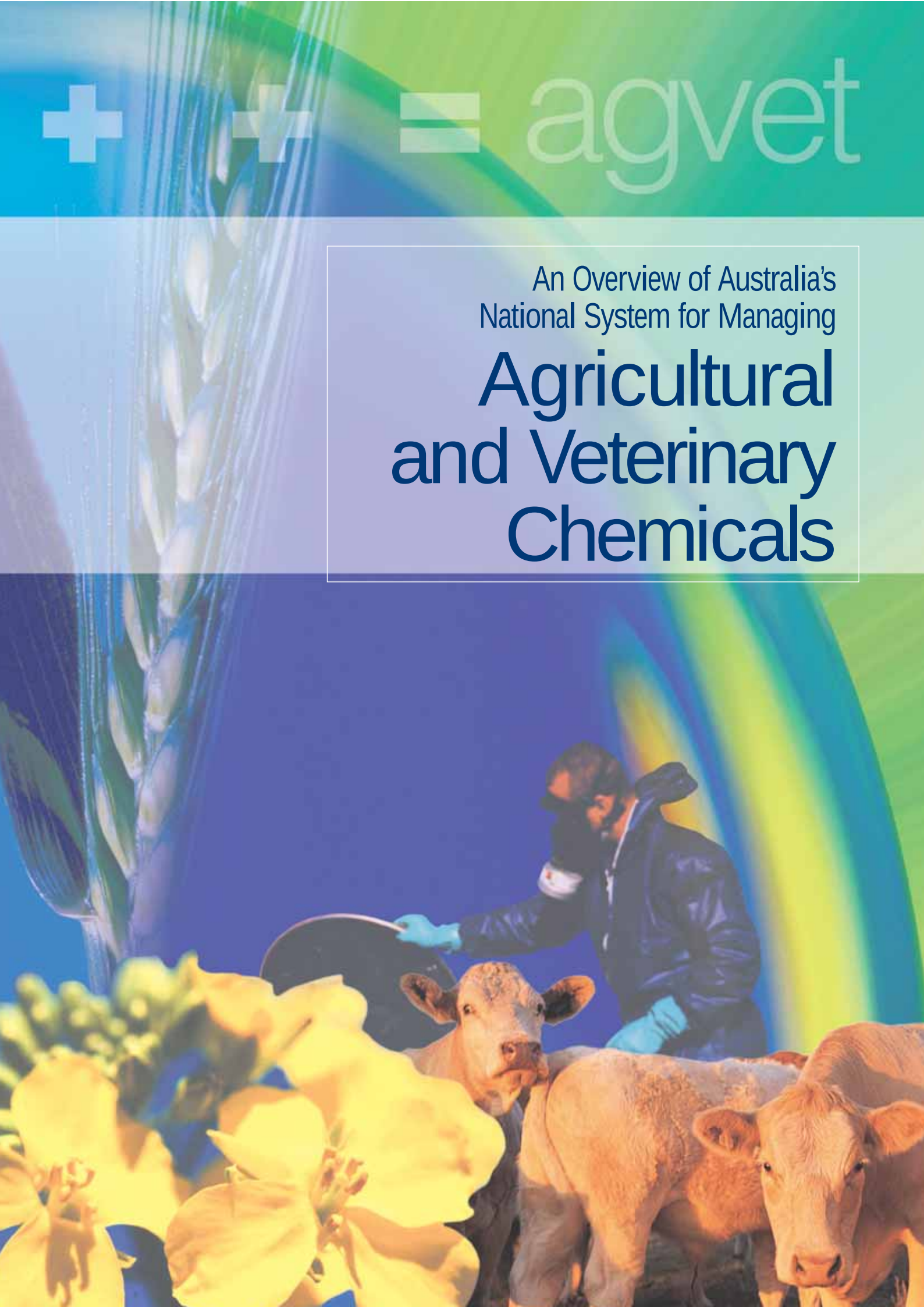
In 2006, the Environment Protection and Heritage Council reviewed the NPI National Environment Protection Measure. While the Council agreed to continue the exclusion of agvet chemicals from the NPI, consideration of including agvet chemicals in the NPI was only deferred until progress with the Department of the Environment and Water Resources (DEW) chemicals monitoring program and its capacity for delivering public access to agvet chemical use data can be assessed.

The agvet chemical industry is concerned that if agvet chemicals were to be included in the NPI, reporting obligations would impose additional regulatory requirements on business. As noted above, under the NChEM framework, the Department of the Environment and Water Resources (DEW) is currently scoping the establishment of a database of chemical use.

agvet

An Overview of Australia's National System for Managing

Agricultural and Veterinary Chemicals



System Development and Leadership

Nationally by PIMC through PSIC, and internationally by the Australian Government

Registration of Agricultural and Veterinary Chemicals

Nationally by APVMA

SYSTEM DEVELOPMENT AND LEADERSHIP

The role of governments in the agricultural and veterinary chemical management system is to develop, manage, evaluate and continually improve the system. This is led at the national level by the **Primary Industries Ministerial Council (PIMC)**, consisting of the agriculture ministers from the Australian Government, the states and territories and New Zealand.

PIMC seeks advice on agricultural and veterinary chemical issues from a committee of experts, the **Product Safety and Integrity Committee (PSIC)**. This committee includes high level representatives from Australian and state/territory government primary industry or agriculture departments, CSIRO and the Australian Pesticides and Veterinary Medicines Authority (APVMA). It also involves representatives of other ministerial councils which have an interest in managing agricultural and veterinary chemicals:

- the Workplace Relations Ministers Council
- the Australian Health Ministers Council and
- the Environment Protection and Heritage Council.

PSIC also works with non-government organisations representing the agricultural and veterinary chemical industry, agricultural industries, professional and research institutions and community health, consumer and environmental interests at the national level.

REGISTRATION OF AGRICULTURAL AND VETERINARY CHEMICALS

The Australian Pesticides and Veterinary Medicines Authority (APVMA) administers the National Registration Scheme for Agricultural and Veterinary Chemicals. The Scheme registers and regulates the manufacture and supply of all pesticides and veterinary medicines used in Australia, up to the point of wholesale sale.

Before being registered for sale, products must go through a risk assessment process. Companies must provide the APVMA with information about the product to allow independent evaluators to decide whether it is effective and safe for people, animals and the environment, and not a trade risk.

Other Australian Government agencies also help the APVMA evaluate agricultural and veterinary chemical products:

- **The Office of Chemical Safety** (Department of Health and Ageing) advises on toxicological issues and worker safety.
- **The Department of the Environment and Heritage** advises on whether products might harm the environment, and how to avoid this.
- **State/Territory primary industry or agriculture departments, environment protection authorities and independent reviewers** advise on how well the chemicals control pests and diseases.

The APVMA notifies the public of the results of the evaluation and invites public comment on the registration proposal before making its decision. It also invites members of the public to participate in its programs such as reporting adverse chemical experiences through the Adverse Experience Reporting Program (AERP) and contributing to chemical reviews.

The APVMA sets maximum residue limits (MRLs). An MRL is the highest concentration of an agricultural and veterinary chemical residue permitted in food or animal feed. MRLs are used to check whether chemical users are following the directions on the label. MRLs are normally set well below the level that would harm health. When an MRL is exceeded, it usually indicates a chemical is being misused, rather than a public health or safety concern.

The APVMA and **Food Standards Australia New Zealand (FSANZ)** work together to ensure that the use of chemical products and the level of any residues in food are safe. When a new MRL is set by the APVMA, it notifies FSANZ so that it can be considered for listing in the Food Standards Code. When incorporated into the Food Standards Code, the MRL is the highest concentration of a chemical residue that is legally permitted in a food.

The APVMA reviews products that have been on the market for many years to ensure they meet the latest standards. Its national compliance program also ensures chemical products continue to meet their registration conditions.

For further information visit the following websites:

- APVMA at www.apvma.gov.au
- FSANZ at www.foodstandards.gov.au

Control of Use

Jurisdictionally by State and Territory Governments

CONTROL OF USE

State and territory governments regulate the use of agricultural and veterinary chemicals after they have been sold. The regulations cover:

- basic training requirements for users
- licensing of commercial pest control operators and ground and aerial spray operators
- residue monitoring
- arrangements to enforce the safe use of chemicals, including the use of codes of practice, spraydrift guidelines and other user awareness raising initiatives.

State and territory regulations use a national model to regulate dangerous substances in the workplace.

State and territory government primary industry/agriculture, health and environment agencies also advise on agricultural and veterinary chemical use and promote other means of controlling pests and diseases. They undertake research, training and education to manage possible risks from agricultural and veterinary chemical use and to improve the way they are used.

For further information visit the following websites

- NSW Department of Primary Industries at www.dpi.nsw.gov.au
- Victorian Department of Primary Industries at www.dpi.vic.gov.au
- Queensland Department of Primary Industries and Fisheries at www.dpi.qld.gov.au
- Tasmanian Department of Primary Industries Water and Environment at www.dpiwe.tas.gov.au
- Department of Primary Industries and Resources South Australia at www.pirsa.sa.gov.au
- Western Australian Department of Health at www.health.wa.gov.au
- Northern Territory Department of Business, Industry and Resource Development at www.primaryindustry.nt.gov.au

Industry Risk Management Programs (Manufacturers & Distributors)

Nationally by agricultural and veterinary chemical industry organisations

INDUSTRY RISK MANAGEMENT PROGRAMS

(Manufacturers and Distributors)

Avcare (the National Association for Crop Production and Animal Health) is the largest national organisation representing the agricultural and veterinary chemical industry. It includes manufacturers, formulators, chemical distributors and companies involved in agricultural biotechnology.

VMDA (the Veterinary Manufacturers and Distributors Association), represents the interests of the Australian animal health industry, including manufacturers, importers and distributors of veterinary medicines and animal health products.

Avcare and VMDA work with the APVMA and government to ensure a fair, science-based registration system for agricultural and veterinary chemicals.

Agsafe is an independent subsidiary of Avcare. Its role is to help the industry to safely store, handle and transport chemicals through accredited training and safety programs. The program also provides national training and accreditation programs to those selling or offering advice on agricultural and veterinary chemicals, to ensure agricultural and veterinary chemical users get responsible advice. Agsafe uses commercial sanctions authorised by the Australian Competition and Consumer Commission (ACCC) to ensure the industry meets its obligations.

VMDA runs a veterinary industry focussed training program which is Agsafe accredited.

State and territory governments recognise the Agsafe program in relation to licensing requirements and by granting exemptions to Agsafe-accredited premises.

Agsafe also manages ***drumMUSTER,*** a national program for collecting and recycling empty, cleaned, non-returnable chemical containers. The program aims to have fewer containers ending up as landfill by providing farmers with a safe way of safely disposing of them, and a cleaner environment.

ChemClear® is a new industry-funded program which aims to provide all chemical users with a safe and easy collection and disposal service.

For further information visit the following websites:

- Avcare at www.avcare.org.au
- *drumMUSTER* at www.drummuster.com.au
- Chemclear® at www.chemclear.com.au
- VMDA at www.vmda.com.au

Industry Risk Management Programs (Users)

Nationally/industry sector by primary industry organisations

+

System Improvement

Lead by Government (PIMC through PSIC)

=

Agricultural and Veterinary Chemical Management System

INDUSTRY RISK MANAGEMENT PROGRAMS

(Users)

Some agricultural and veterinary chemical training providers run training and accreditation programs to ensure safe and effective chemical use.

The National Farmers' Federation and the Rural Training Council of Australia set up ***ChemCert Australia*** as a national industry training and accreditation program, based on recognised national industry competencies. ChemCert trains farm chemical users to meet all regulations and laws requiring the safe use of agricultural and veterinary chemicals, as well as their obligations under industry quality assurance programs.

The Australian Centre for Agricultural Health and Safety and *Farmsafe* Australia's ***Managing Farm Safety*** training course trains farm managers and owners to meet national industry competency standards for occupational health and safety. Its aim is to manage injury and illness risks associated with farm life and work, including agricultural and veterinary chemical use.

Other quality assurance programs and codes of practice for primary industries and regions include managing the risks of agricultural and veterinary chemical use on-farm. More farmers are adopting these programs to ensure they meet their food safety and wider community obligations. Major retailers and fresh produce handlers also have supplier quality-assurance programs to ensure food safety and quality.

For further information visit the following websites:

- National Farmers' Federation at www.nff.org.au
- ChemCert at www.Chemcert.org.au
- Farmsafe at www.farmsafe.org.au

SYSTEM IMPROVEMENT

A critical part of the system is assessing how well it is meeting its objective, so improvements can be made, if necessary. **National operating principles** are being developed to monitor and report on the system's performance and to identify areas for improvement. The principles describe what the system wants to achieve. This includes:

- an effective registration process and system for managing risks associated with agricultural and veterinary chemical sales, handling, use and disposal
- consistent regulatory approaches and compliance costs for primary producers across Australia
- fair arrangements for meeting the costs of managing risks
- a way to evaluate and communicate how well the system is working to give everyone involved, confidence.

In partnership with participating industries, the Australian Government Department of Agriculture, Fisheries and Forestry conducts the **National Residue Survey (NRS)**, which monitors chemical residues in raw food and fibre commodities. Participating industries—meat, grains, honey, fruit, vegetables, nuts, seafood, and wool—pay for the NRS.

The NRS also surveys heavy metals and organochlorines, such as DDT, that could still be present in the environment as a result of past industry use.

The APVMA runs **Adverse Experience Reporting Programs** to report on unintended or unexpected effects of agricultural and veterinary chemicals on animals, people or the environment. The APVMA analyses the reports to develop better practices for using chemicals, prevent avoidable side effects and to continually improve manufacturing practices. Anyone can participate in these reporting programs.

FSANZ conducts the **Australian Total Dietary Survey**, which screens food prepared to table-ready state. The survey estimates the dietary intake of a range of pesticides and contaminants, based on food consumption data from national dietary surveys. This provides the most accurate estimates available of our exposure to agricultural and veterinary chemicals through our food.

Residue-testing programs undertaken by the states/ territories and by agricultural commodity organisations identify and help correct failings in agricultural practice, the quality of chemical products and MRL problems. Some marketing organisations also conduct their own residue surveys as part of their quality assurance arrangements.

Stakeholders groups can provide feedback on the performance of the agricultural and veterinary chemical management system through APVMA stakeholder consultative committee, chemical registration and review processes and through their participation in PSIC policy development processes.

For further information visit the following websites:

- APVMA at www.apvma.gov.au
- FSANZ at www.foodstandards.gov.au

What are agricultural and veterinary chemicals and why are they used?

Chemicals are used in industrial processes, agriculture, veterinary and pharmaceutical medicines and in food as food additives. They may also be present in food as contaminants.

Agricultural and veterinary chemicals are used to protect crops, livestock and other animals and plants from pests and diseases. They include pesticides, such as insecticides, fungicides and herbicides, and veterinary medicines.

Agricultural and veterinary chemicals help agricultural industries to be more productive and competitive on world markets, and to improve produce quality.

In the wider community, we use them to control pests and weeds in our gardens, as well as in our national parks and nature reserves, and to help control disease-carrying insects, such as mosquitos.

However, we – and people overseas who buy our agricultural produce – need to be confident agricultural and veterinary chemicals are safe to use and are used responsibly.

Managing agricultural and veterinary chemical use

Australia's system for managing agricultural and veterinary chemicals is a risk management system designed to give us confidence that they are safe to use and are used responsibly.

It also encourages us to rely less on these chemicals, where possible, by using natural means to control pests and diseases.

There are six steps in the system with a range of strategies designed to manage the possible risks to people, the environment and trade associated with different aspects of agricultural and veterinary chemical use in Australia. Added together, they deliver a national system for managing agricultural and veterinary chemicals from manufacture to disposal:

System Development and Leadership
+ Registration of Agricultural and Veterinary Chemicals
+ Control of Use
+ Industry Risk Management Programs (Manufacturers and Distributors)
+ Industry Risk Management Programs (Users)
+ System Improvement
= Agricultural and Veterinary Chemical Management System

The strategies involve the Australian Government, state and territory governments, agricultural and veterinary chemical manufacturers and users and the general community. Some are applied at a national level, others at an industry, state or local level.

Australia is also active at the international level on agricultural and veterinary chemical issues, such as setting standards for chemical use and for reporting on their use. Australia's participation in international organisations like the Organisation for Economic Cooperation and Development (OECD) and in a range of United Nations programs is led by the Australian Government and enables us to have access to the latest information on agricultural and veterinary chemicals and keeps us up to date in managing the risks associated with them.

For information about other chemicals used in Australia, visit the National Chemical Information Gateway website at www.deh.gov.au/chemicals-gateway.

Useful Contacts

APVMA
General enquiries
Phone: 02 6272 5852 within Australia or +61 2 6272 5852
Email: contact@apvma.gov.au

Community Consultative Committee
Email: ccc@apvma.gov.au

Adverse experiences with agricultural or veterinary chemicals (AERP)
Phone: 02 6272 3651 within Australia or +61 2 6272 3651
Fax: 02 6271 6442 within Australia or +61 2 6271 6442

FSANZ
Phone: 02 6271 2222 within Australia or +61 2 6271 2222

Department of Environment and Heritage
Phone: 02 6274 1111 within Australia or +61 2 6274 1111

National Occupational Health and Safety Commission
Phone: 02 6279 1000 within Australia or +61 2 6279 1000
Email: info@nohsc.gov.au

Office of Chemical Safety
Web: www.tga.gov.au/chemicals/ocs
Phone: 02 6270 4300 within Australia or +61 2 6270 4300

NSW Department of Primary Industries
Phone: 02 6391 3336 within Australia or +61 2 6391 3336
Email: nsw.agriculture@agric.nsw.gov.au

Victorian Department of Primary Industries
Phone: 136 186 within Australia or +61 3 5332 5000
Email: customer.service@dpi.vic.gov.au

Queensland Department of Primary Industries
Phone: 13 25 23 within Australia or +61 7 3404 6999
Email: callweb@dpi.qld.gov.au

Primary Industries and Resources South Australia
Phone: 08 8226 0549 within Australia or +61 8 8226 0549
Email: PIRSA.RuralChemicals@saugov.sa.gov.au

Tasmanian Department of Primary Industries Water and Environment
Phone: 1300 368 550 within Australia or +61 3 6233 8011

Western Australian Department of Agriculture
Phone: 08 9368 3333 within Australia or +61 8 9368 3333

Northern Territory Department of Business, Industry and Resource Management
Phone: 08 8999 2311 within Australia or +61 8 8999 2311

Avcare/Agsafe/*drumMUSTER*/ChemClear
Phone: 02 6230 6399 within Australia or +61 2 6230 6399
Email: info@avcare.org.au

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Phone: 07 3374 0311 within Australia or +61 7 3374 0311
Email: vmda@vmda.org.au

National Farmers' Federation
Phone: 02 6273 3855 within Australia or +61 2 6273 3855

ChemCert
Phone: 02 6161 0477 within Australia or +61 2 6161 0477
Email: national@chemcert.org.au

Farmsafe
Phone: 02 6752 8218 within Australia or +61 2 6752 8218
Email: info@farmsafe.org.au

National Residue Survey
Phone: 02 6272 3446 within Australia or +61 2 6272 3446
Email: nrs@daff.gov.au

National Toxics Network
Web: www.oztoxics.org
Phone: 02 6288 5881 within Australia or +61 2 6288 5881
Email: biomat@oztoxics.org

Product Safety and Integrity Committee
for Primary Industries Standing Committee
Email: psic@daff.gov.au